

Remarks

In response to the Office Action dated February 16, 2005, Applicants provide the following arguments and remarks. Claims 2, 10, 14-22, 24, 27-35, 37, 39-43, 45-47 and 49-77 have been canceled without prejudice. Claims 1, 3, 4, 9, 11, 12, 23, 25, 26 36, and 38 have been amended. Claims 78-81 have been added. No new matter has been added.

Rejections under 35 U.S.C. §112

Claims 1-13, 23-26, 36-38, 44 and 48 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the application was filed, was in possession of the claimed invention. Applicants respectfully traverse the rejection and note that it is moot with respect to the canceled claims.

Applicants note that the claims have been amended to recite not all canine amelogenin genes, but rather those genes “wherein one primer binds to a sequence of SEQ ID NO:22 and to a sequence of SEQ ID NO:23”. The binding of the primers to detect a difference between the canine amelogenin gene on the Y chromosome and the canine amelogenin gene on the X chromosome determines gender of the canine subject. Applicants have provided ample teachings with respect to these particular genes on the X and Y chromosome and primers useful for amplifying such sequences (See for example, pages 27-34 of the application as filed). Thus, in light of the claim amendments, Applicants have specified the sequence of the canine amelogenin gene that is the subject of the invention.

Accordingly, Applicants request that the rejection under U.S.C. §112, first paragraph, be withdrawn.

Claims 1-13, 23-26, 36-38, 44 and 48 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that is not described in the specification in a way that would enable one skilled in the art to make and/or use the invention. Applicants respectfully traverse the rejection and note that it is moot with respect to the canceled claims.

Applicants note that the claims have been amended to recite not all canine amelogenin genes, but rather those genes “wherein one primer pair can bind to the sequence of SEQ ID NO:22 and SEQ ID NO:23”. The binding of the primers to detect a difference between the canine amelogenin gene on the Y chromosome and the canine amelogenin gene on the X chromosome determines gender of the canine subject. The primers generate amplification products that are distinguishable including, for example, products for the X and Y chromosome of 1-143 nucleotides (SEQ ID NO:10) and 1-146 nucleotides (SEQ ID NO:11), respectfully based on particular regions of SEQ ID NO:22 and SEQ ID NO:23 (see also paragraph [00107] and Tables 1-7, especially Table 3).

Applicants have provided ample teachings with respect to these particular genes on the X and Y chromosome and primers useful for amplifying such sequences (See for example, pages 27-34 of the application as filed). It is unclear to Applicants where the examiner’s confusion is with respect to target sequences of the X and Y chromosome and exemplary primers because all of the sequence information is explicitly described in the Examples of the application on pages 27-34 of the application. Thus, in light of the claim amendments, Applicants have specified the sequence of the canine amelogenin gene that is the subject of the invention. Accordingly, Applicants request that the rejection under U.S.C. §112, first paragraph, be withdrawn.

Claims 1-13, 23-26, 36-38, 44 and 48 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse the rejection and note that it is moot with respect to the canceled claims.

A) The Office Action notes that the probe or primer “specifically binds” to particular sequences. The claims have been amended rendering the rejection moot. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 23 and 36 stand rejected under 35 U.S.C. §102(a) as allegedly anticipated by Tachi et al. Applicants respectfully traverse this rejection.

Tachi et al. is cited for describing PCR analysis using a primer pair designed from the lupine X-linked AMELX partial coding sequence. Tachi et al. have described two putative alleles from each to the X chromosomes from a female pelt. Applicants submit that Tachi et al. does not describe a primer pair that binds to a sequence of SEQ ID NO:22 and SEQ ID NO:23, which is required by claims 23 and 36. Further, Applicants have added new claims 78-79 which are directed to dogs, wherein Tachi et al. is limited to teachings regarding an extinct wolf which “remains a taxonomical or phylogenetic enigma” and is considerably different in sequence at this site from both the domestic dog and Mongolian wolf. Thus, since Tachi et al. fail to teach each and every element of claims 23 and 36, it cannot anticipate the claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 23 and 36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Asano et al. Applicants respectfully traverse this rejection.

Applicants submit that Asano et al. does not describe a primer pair that binds to a sequence of SEQ ID NO:22 and SEQ ID NO:23, which is required by claims 23 and 36. Asano et al. is cited for teaching the study of recovery of genomic DNA and functional genes from several mammalian pelt specimens, and in particular a fragment of the X-linked amelogenin gene

(AMELX). This fragment cited by both Asano et al. and Tachi et al. is 3646 bp downstream (in human gene terms) of SEQ ID NO: 22 and SEQ ID NO: 23 and does not detect a difference between the amelogenin gene on the Y chromosome and the amelogenin gene on the X chromosome nor does it determine gender of the subject. Thus, since Asano et al. fail to teach each and every element of claims 23 and 36, it cannot anticipate the claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 23 and 36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Yuasa et al. Applicants respectfully traverse this rejection.

Applicants submit that Yuasa et al. does not describe a primer pair that binds to the sequence of SEQ ID NO:22 and SEQ ID NO:23, which is required by claims 23 and 36. Yuasa et al. is cited for teaching the amplification of a single amelogenin cDNA of unknown X or Y chromosome origin using PCR primers. This fragment is 3311 bp downstream (in human gene terms) of SEQ ID NO: 22 and SEQ ID NO: 23 and is from a highly conserved region and being cDNA, does not include intronic sequences. Yuasa is silent with respect to using primers to amplify the amelogenin gene from the X and Y chromosome of a subject, which is required in amended claims 23 and 36. Thus, since Yuasa et al. fail to teach each and every element of claims 23 and 36, it cannot anticipate the claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection.

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Applicants submit that the claims are in condition for allowance and request such action.

A check in the amount of \$510.00 is enclosed to cover the three-month extension of time fee. If any additional fees are due, the Commissioner is hereby authorized to charge any fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 07-1896.

Respectfully submitted,

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